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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/380,579 09/07/99 IKEHARA

S Q55691 VB

EXAMINER

VANDER VEGT, F

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED:

12/01/00

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WASHINGTON DC 20037-3202

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/380,579

Applicant(s)

Ikehara et al

Examiner

F. Pierre VanderVegt

Group Art Unit

1644



☐ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-8 ~~is~~/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 ~~is~~/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 4, 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a rule 371 continuation of PCT application PCT/JP98/00909.
Applicant should amend the specification at page 1 to reflect the priority information.

Claims 1-8 are currently pending in this application.

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Claim Rejections - 35 USC § 112

1. Claims 1, 2, 5, 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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Claims 1, 2, 5 and 6 are indefinite in the recitation of "portal." The term has multiple meanings in medical usage, most broadly reading upon any gateway or entrance including, for example, a "portal" for medicament addition on an intravenous 'drip' apparatus. If Applicant's intent is the hepatic portal vein, this should be more clearly conveyed in the claims.

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Claim 8 recites the use of a tolerogen comprising hematopoietic stem cells, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process Applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

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2. Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zhang et al (1D on form PTO-1449 filed 12/9/1999).

10 The Zhang et al reference teaches the administration to a subject of a first composition comprising allogeneic bone marrow cells enriched for hematopoietic stem cells via the recipients hepatic portal vein. Zhang et al further teaches the intravenous administration of allogeneic bone marrow cells enriched for hematopoietic stem cells to the same subjects (Abstract in particular). Zhang et al further teaches that this protocol resulted in a tolerant state which persisted more than 15 49 days (Abstract in particular). Zhang et al also teaches that injection of bone marrow cells via the hepatic portal vein suppresses donor-specific rejection (page 1563, second column in particular) and that administration of donor antigens via the hepatic portal vein results in the increased survival of cardiac and renal grafts (page 1563, first column in particular), i.e., graft tolerance. The prior art teaching clearly anticipates the claimed invention. Claims 3 and 4 are 20 included because the composition is not altered by its intended use with radiotherapy and is the same as the composition taught by Zhang et al. Applicant is reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). Claim 8 is included because it is a "Use" claim which recites no positive steps and therefore can read upon the composition being used as well as any method 'using' said 25 composition.

4. Claims 1-4 and 7-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Orloff et al (U on form PTO-892).

30 The Orloff et al reference teaches a method of inducing specific allogeneic tolerance to a transplanted organ. Orloff et al teaches the lethal irradiation of host animals followed by their

reconstitution with T cell depleted allogeneic bone marrow cells. Orloff et al further teaches that the treatment results in the establishment of hematopoietic chimerism. Orloff et al also teaches the transplantation of small bowel to the chimeric animals. Orloff et al teaches that graft survival in chimeric animals ranged from more than 135 to more than 304 days with no signs of rejection in any animals. This is compared to a median graft survival of only 8 days in control animals. The prior art teaching clearly anticipates the claimed invention. Claims 1 and 2 are included because the composition is not altered by its intended use with portal administration and is the same as the composition taught by Orloff et al. Applicant is reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). Claim 8 is included because it is a "Use" claim which recites no positive steps and therefore can read upon the composition being used as well as any method 'using' said composition.

5. Claims 1-4 and 7-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sharabi et al (U on form PTO-892).

The Sharabi et al reference teaches a method for the induction of specific tolerance to a transplanted xenogeneic organ. Sharabi et al teaches whole body irradiation of a subject animal followed by infusion of T cell depleted xenogeneic bone marrow cells. Sharabi et al teaches that donor type xenogeneic skin grafts placed 4 months after bone marrow transplantation were accepted, while skin grafts allogeneic to the donor were rapidly rejected. The prior art teaching clearly anticipates the claimed invention. Claims 1 and 2 are included because the composition is not altered by its intended use with portal administration and is the same as the composition taught by Orloff et al. Applicant is reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). Claim 8 is included because it is a "Use" claim which recites no positive steps and therefore can read upon the composition being used as well as any method 'using' said composition.

Conclusion


6. The Zhang et al reference cited on the form PTO-1449 filed May 3, 2000 has been lined through because it is a duplicate of the Zhang et al reference earlier cited on the form PTO-1449 filed December 9, 1999. In the future, it is respectfully suggested that Applicant's representative
5 list references on form PTO-1449 with author names preceding the title and journal name.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

10 8. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official
15 documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's
20 voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

25 F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
November 29, 2000


F. PIERRE VANDERVEGT
PATENT EXAMINER